PATENT
Customer Number 22,852
Attorney Docket No. 07873.0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Solco Walle SCHALM	)	Group Art Unit: 1648
	)	
Application No.: 09/689,637	)	Examiner: L. Scheiner
	)	
Filed: October 13, 2000	)	**Attn: BOX PATENT EXT.**
	)	
For: COMBINED HEPATITIS B TREATMENT	)	
	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(b)

This Application for Patent Term Adjustment requests reconsideration of the Determination of Patent Term Adjustment ("PTO Determination") under 35 U.S.C. 154(b) received with the Notice of Allowance papers for this patent application. Applicant encloses a copy of the PTO Determination as Attachment A. Attachment B includes the PTO patent term adjustment calculation obtained from the PAIR system.

This Application is being filed concurrently with the issue fee payment for the patent application. The Application is therefore being filed in a timely manner under the provisions of 37 C.F.R. § 1.705(b). Applicant encloses the fee of $200.00 set forth in 37 C.F.R. § 1.18(e) in support of this Application.

The patent application was filed on October 13, 2000, and is thus eligible for patent term adjustment under 37 C.F.R. § 1.702. The patent application is not subject to a terminal disclaimer. The PTO Determination states that the patent term adjustment for this patent application is **0** days. This is incorrect. The correct patent term adjustment for this patent application should be **640** days.

First, the patent term adjustment calculation shown in Attachment B indicates a delay by applicant of 96 days. This calculation is incorrect, and should be 61 days. The PTO mailed a Notice of Missing Parts on November 28, 2000. Applicant responded fully to the Notice on April 30, 2001. A copy of a stamped postcard for this response is enclosed in Attachment C. The time period between February 28, 2001 (three months from the mailing of the Notice of Missing Parts) and April 30, 2001, is 61 days.

Second, during substantive prosecution, the PTO mailed an Office Action on September 25, 2001. Applicant responded to that Office Action on December 21, 2001. Attachment D encloses a copy of the response as well as a copy of a stamped postcard indicating receipt of the response in the PTO on December 21, 2001. Under 37 C.F.R. § 1.702(a)(2), the PTO was expected to respond to applicant's reply not later than four months after the December 21, 2001, filing date of the reply. The Office, however, did not respond until the mailing of the Notice of Allowance on March 22, 2004. The period of adjustment for this delay on the part of the PTO is 701 days.

The applicant is unaware of any circumstances between the filing of the response on December 21, 2001, and the mailing of the Notice of Allowance, that would have constituted a failure to engage in reasonable effects to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704. More particularly, the applicant does not agree with the calculation of 668 days of applicant delay.

After not receiving a response from the PTO (to applicant's reply filed on December 21, 2001), the applicant filed a Status Inquiry on August 23, 2002. A copy of the status inquiry and corresponding PTO-stamped postcard is enclosed in Attachment E. After still not receiving a response from the PTO by May 15, 2003, the applicant filed a "Re-submission of Response." A copy of that document and the corresponding PTO-stamped postcard is in Attachment F. The Re-submission explained that the undersigned spoke with the Examiner, who indicated that perhaps certain docket entries for action on the case in the PTO may not have been entered. **As explained in the Re-submission, the applicant followed the Examiner's instructions to re-submit the earlier response of December 21, 2001.**

By August 12, 2003, applicant had not received a response from the PTO. Attachment G contains a copy of another status inquiry filed on that date and the corresponding PTO-stamped postcard. On October 20, 2003, still after not receiving any response from the PTO, the undersigned again re-sent a copy of the December 21, 2001, response to the Examiner. *See* Attachment H. On March 22, 2004, the PTO finally responded by mailing a Notice of Allowance.

As is clear from all of the above, the entire delay between December 21, 2001 and March 22, 2004, is on the part of the PTO.

In light of the above, the appropriate patent term adjustment is 640 days.

Please grant any extensions of time required to enter this Application and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 22, 2004

By: _____
Steven J. Scott
Reg. No. 43,911

7873.0002

1500/SJS

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: Solco Walle SCHALM

Serial No.: 09/689,637 Group Art Unit: 1614

Filed: October 13, 2000 Examiner: Unassigned

For: COMBINED HEPATITIS B TREATMENT

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1. Transmittal Letter with a 3-month Extension of Time ($445.00 small entity)
2. Response to Notice to File Missing Parts ($65.00 late filing fee)
3. Copy of Notice to File Missing Parts
4. Declaration
5. Preliminary Amendment
6. Check for $510.00

Dated: April 30, 2001 (Monday)

Docket No.: 07873.0002-00 (Due Date: April 28, 2001)

SJS/K. Cassin - Mail Drop 222

DKO 4-30-01 TJ

7873.0002 BCO/SJS

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: **Solco Walle SCHALM**

Serial No.: 09/689,637 Group Art Unit: 1648

Filed: October 13, 2000 Examiner: L. Scheiner

For: COMBINED HEPATITIS B TREATMENT

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1. Response

Dated December 21, 2001

Docket No.: 07873.0002

SJS/bas - **Please return to** Mail Drop 222

(Due Date: 12/25/01)

DHS 12-21-01

PATENT
Customer Number 22,852
Attorney Docket No. 07873.0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Solco Walle SCHALM	)	Group Art Unit: 1648
	)	
Application No.: 09/689,637	)	Examiner: L. Scheiner
	)	
Filed: October 13, 2000	)	
	)	
For: COMBINED HEPATITIS B TREATMENT	)	
	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Response

This communication responds to the Office Action dated September 25, 2001. Please reconsider this application in light of the following remarks.

I. Status of claims

Claims 11-20 are pending in this application. The Examiner has indicated that claim 17 is drawn to allowable subject matter and that claims 11-16 and 18-20 are rejected.

II. Format of the claims

The Examiner suggested that applicants write the pending claims in Jepson format. Applicants respectfully decline the Examiner's invitation. The claims as they stand conform to the applicable requirement of definiteness in 35 U.S.C. § 112, second paragraph, so there should be no need to re-write the claims.

III. Rejection of claims 1-16 and 18-20 under 35 U.S.C. § 103(a)

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

The Examiner rejected claims 1-16 and 18-20 under 35 U.S.C. § 103(a) as unpatentable over Nicoll et al., Journal of Gastroenterology and Hepatology, vol. 12, pp. 843-854 (1997) ("Nicoll"). In support of the rejection, the Examiner commented that Nicole discloses the nucleoside analog "adefovir," and discloses that adefovir has been shown to increase the activity of natural killer cells and stimulate immune responsiveness, most likely through endogenous interferon-α production.

The Examiner acknowledged that Nicoll does not disclose a combination therapy of adefovir with interferon-α, and also does not disclose the 26 week protocol used in the present claims. The Examiner concluded that it would have been obvious to administer adefovir in combination with interferon-α for the treatment of hepatitis B virus, in light of the comment that adefovir may stimulate immune responsiveness though endogenous interferon-α production. The Examiner also appears to have admitted that Nicoll fails to enable a treatment protocol of more than 26 weeks. Applicants respectfully traverse this rejection.

Claim 11, the only independent claim in this application, recites a method of treating a human patient infected with hepatitis B virus, which comprises administering to the patient both a nucleoside analog and interferon-α during a period of at least 26 weeks. In order to establish a *prima facie* case of obviousness of this invention, the Examiner must show, among other things, a motivation in the art to have practiced this method. For the reasons given below, one skilled in the art would not have been motivated to practice the claimed method in light of the Nicoll disclosure. If anything, Nicoll's discussions relating to possible combination therapies actually evidences an uncertainty in the art on the subject, rather than clear guidance to practice the claimed methods.

Nicoll discloses two major classes of agents for the treatment of hepatitis B: immunomodulating agents such as interferons, and direct antiviral agents such as nucleoside analogs. The article comments on the use of those agents alone, and also speculates on possible combination therapies. Many of Nicoll's comments on possible combination therapies appear, admittedly by Nicole

LAW OFFICES
INNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

herself, as only speculation. For example, the last sentence of the Abstract states that "[i]n this article, we . . . speculate on promising approaches with combination chemotherapy . . . ." Furthermore, at the end of the article at page 850, Nicoll concludes that "[t]here is not enough information to make predictions concerning combination chemotherapies." The author's conclusions in her own article thus appear to contradict the Examiner's belief that the combination therapy now claimed would have been obvious in view of the very same text.

When Nicoll does speak favorably of potential in combination therapies, she speaks in terms of combination of two nucleoside analogs, rather than a combination of interferon-α with a nucleoside analog. Indeed, at page 849, Nicoll cites to three prior trials of combination therapy of interferon-α with a nucleoside analog, and concludes that the therapy "has shown no improvement over IFN-α alone." Those cited treatments, incidentally, did not extend for at least 26 weeks as is done in the present methods. Nicoll goes on to say on the same page that "[t]he strategy of combining antiviral agents such as nucleoside analogs with immunomodulators may need to be reappraised," and that "combinations of two nucleoside analogs, such as famciclovir and lamivudine may be synergistic and offer more therapeutic potential." Thus, Nicoll itself appears to teach away from, not towards, a combination therapy of interferon-α with a nucleoside analog.

The Examiner commented that "it would not appear that tandem adefovir/interferon administration would be contraindicated since IFN levels are boosted by" adefovir. On a legal level, the test of obviousness is not whether something is "not contraindicated." Something could very well be "not contraindicated," but that is not enough to make it obvious. Instead, the person skilled in the art must have an affirmative motivation to do what the applicants have done. On a factual level, the possible action of adefovir as an interferon inducer has not led, in applicant's experience or knowledge, to documented clinical effects. Furthermore, Nicoll's own expressed doubts about combination therapy of interferon-α and nucleoside analogs in general appear to contradict the Examiner's belief that the combination therapy now claimed would have been

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

obvious in view of the very same text. In her comments on the problems with combination therapies, Nicoll particularly made no special exception for adefovir apart from all other nucleoside analogs discussed. Furthermore, given the lack of success with other nucleoside analogs, those skilled in the art would not have had an expectation of success in using adefovir in combination with interferon-α.

The Examiner further commented that Nicoll fails to enable a more than 26 week treatment protocol. Applicants acknowledge that Nicoll does not suggest the claimed treatment that lasts of a period of at least 26 weeks.

The Examiner also stated that the present specification fails to enable the combination therapy of interferon-α and adefovir, because the working example in the specification discloses results for a patient receiving a combination therapy of interferon-α and lamivudine. The Examiner did not, however, reject any claims as non-enabled. The specification does enable the full scope of the claims. With regard to a possible combination therapy of interferon-α and adefovir specifically, the specification identifies adefovir as an example nucleoside analog, and states that it may be administered, for example, in a dose of between 5 and 30 mg per day. Specification at page 4, lines 34-35. The specification also states that interferon-α may be administered, for example, between 30 megaUnits and 15 megaUnits per week. Specification at page 5, lines 11-13. It would be a matter of routine for those skilled in the art to follow the guidance set forth in the specification to administer this combination therapy or any other specific type of therapy embraced by the claims.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

In light of the above, the pending claims should be in condition for allowance. Please grant any extensions of time required to enter this Response and charge any additional fees required to our Deposit Account No. 06-0916.

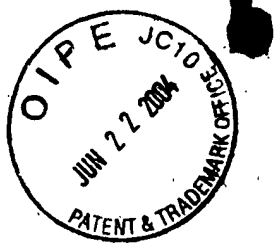
Respectfully submitted,

FINNEGAN, HENDERSON,
FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 21, 2001

By: _____
Steven J. Scott
Reg. No. 43,911

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000



BCOLSJS

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: **Solco Walle SCHALM**

Application No.: 09/689,637 Group Art Unit: 1648

Filed: October 13, 2000 Examiner: L. Scheiner

For: COMBINED HEPATITIS B TREATMENT

---

1. Status Inquiry

Dated August 23, 2002

Docket No.: 07873.0002

SJS/bas - please return to B. Sprow - Mail Drop 1006

PATENT
Customer Number 22,852
Attorney Docket No. 07873.0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Solco Walle SCHALM	Group Art Unit: 1648
Application No.: 09/689,637	Examiner: L. Scheiner
Filed: October 13, 2000	
For: COMBINED HEPATITIS B TREATMENT	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Status Inquiry

Applicants filed a response to an Office Action in this application on December 21, 2001. To date, applicants have not yet received any communication replying to the response filed on December 21, 2001.

In view of these circumstances, the undersigned attorney respectfully requests that the Office advise him of the status of this application as soon as possible in order to determine whether further action by the applicant is needed at this time.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 23, 2002

By: _____
Steven J. Scott
Reg. No. 43,911

7873.0002

B&J55

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: **Solco Walle SCHALM**
Application No.: 09/689,637
Filed: October 13, 2000
For: COMBINED HEPATITIS B TREATMENT

Group Art Unit: 1648
Examiner: L. Scheiner

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1. Re-submission of Response Under 37 C.F.R §1.111

Dated May 15, 2003
Docket No.: 07873.0002
SJS/V. Simmons - Mail Drop 848

Old Sheet

PATENT
Customer Number 22,852
Attorney Docket No. 07873.0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Solco Walle SCHALM	Group Art Unit: 1648
Application No.: 09/689,637	Examiner: L. Scheiner
Filed: October 13, 2000	
For: COMBINED HEPATITIS B TREATMENT	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Re-submission of Response Under 37 C.F.R. § 1.111

On December 21, 2001, applicants filed a Response under 37 C.F.R. § 1.111 to the non-Final Office Action dated September 25, 2001. That Office Action supplemented an earlier Office Action dated July 3, 2001. To date, applicants have not yet received any communication from the Office in reply to the Response filed on December 21, 2001.

The undersigned discussed the status of this application with Examiner Scheiner on May 13, 2003. During that conversation, the Examiner suggested that the Response filed on December 21, 2001, may not have been appropriately docketed and entered by the Office. The Examiner therefore recommended that the undersigned re-submit a copy of the earlier Response.

In view of the above, a copy of the earlier Response is enclosed, together with a copy of a postcard stamped by the Office indicating receipt of the Response on December 21, 2001. Applicant looks forward to receiving the next communication from the Office.

Please grant any extensions of time required to enter this Re-submission of Response and charge any additional fees required to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: May 15, 2003

By: _____

Steven J. Scott
Reg. No. 43,911

7873.0002 BCO/SJS

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: **Solco Walle SCHALM**

Serial No.: 09/689,637 Group Art Unit: 1648

Filed: October 13, 2000 Examiner: L. Scheiner

For: COMBINED HEPATITIS B TREATMENT

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1. Response

Dated December 21, 2001

Docket No.: 07873.0002 (Due Date: 12/25/01)

SJS/bas - **Please return to** Mail Drop 222

DMS 12-21-01

PATENT
Customer Number 22,852
Attorney Docket No. 07873.0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Solco Walle SCHALM	)	Group Art Unit: 1648
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Application No.: 09/689,637	)	Examiner: L. Scheiner
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Filed: October 13, 2000	)	
	)	
For: COMBINED HEPATITIS B TREATMENT	)	
	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Response

This communication responds to the Office Action dated September 25, 2001. Please reconsider this application in light of the following remarks.

I. Status of claims

Claims 11-20 are pending in this application. The Examiner has indicated that claim 17 is drawn to allowable subject matter and that claims 11-16 and 18-20 are rejected.

II. Format of the claims

The Examiner suggested that applicants write the pending claims in Jepson format. Applicants respectfully decline the Examiner's invitation. The claims as they stand conform to the applicable requirement of definiteness in 35 U.S.C. § 112, second paragraph, so there should be no need to re-write the claims.

III. Rejection of claims 1-16 and 18-20 under 35 U.S.C. § 103(a)

LAW OFFICES
INNEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

The Examiner rejected claims 1-16 and 18-20 under 35 U.S.C. § 103(a) as unpatentable over Nicoll et al., Journal of Gastroenterology and Hepatology, vol. 12, pp. 843-854 (1997) ("Nicoll"). In support of the rejection, the Examiner commented that Nicole discloses the nucleoside analog "adefovir," and discloses that adefovir has been shown to increase the activity of natural killer cells and stimulate immune responsiveness, most likely through endogenous interferon-α production.

The Examiner acknowledged that Nicoll does not disclose a combination therapy of adefovir with interferon-α, and also does not disclose the 26 week protocol used in the present claims. The Examiner concluded that it would have been obvious to administer adefovir in combination with interferon-α for the treatment of hepatitis B virus, in light of the comment that adefovir may stimulate immune responsiveness though endogenous interferon-α production. The Examiner also appears to have admitted that Nicoll fails to enable a treatment protocol of more than 26 weeks. Applicants respectfully traverse this rejection.

Claim 1,1, the only independent claim in this application, recites a method of treating a human patient infected with hepatitis B virus, which comprises administering to the patient both a nucleoside analog and interferon-α during a period of at least 26 weeks. In order to establish a *prima facie* case of obviousness of this invention, the Examiner must show, among other things, a motivation in the art to have practiced this method. For the reasons given below, one skilled in the art would not have been motivated to practice the claimed method in light of the Nicoll disclosure. If anything, Nicoll's discussions relating to possible combination therapies actually evidences an uncertainty in the art on the subject; rather than clear guidance to practice the claimed methods.

Nicoll discloses two major classes of agents for the treatment of hepatitis B: immunomodulating agents such as interferons, and direct antiviral agents such as nucleoside analogs. The article comments on the use of those agents alone, and also speculates on possible combination therapies. Many of Nicoll's comments on possible combination therapies appear, admittedly by Nicole

LAW OFFICES
NNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
'ASHINGTON, DC 20005
202-408-4000

herself, as only speculation. For example, the last sentence of the Abstract states that "[i]n this article, we . . . speculate on promising approaches with combination chemotherapy . . . ." Furthermore, at the end of the article at page 850, Nicoll concludes that "[t]here is not enough information to make predictions concerning combination chemotherapies." The author's conclusions in her own article thus appear to contradict the Examiner's belief that the combination therapy now claimed would have been obvious in view of the very same text.

When Nicoll does speak favorably of potential in combination therapies, she speaks in terms of combination of two nucleoside analogs, rather than a combination of interferon-α with a nucleoside analog. Indeed, at page 849, Nicoll cites to three prior trials of combination therapy of interferon-α with a nucleoside analog, and concludes that the therapy "has shown no improvement over IFN-α alone." Those cited treatments, incidentally, did not extend for at least 26 weeks as is done in the present methods. Nicoll goes on to say on the same page that "[t]he strategy of combining antiviral agents such as nucleoside analogs with immunomodulators may need to be reappraised," and that "combinations of two nucleoside analogs, such as famciclovir and lamivudine may be synergistic and offer more therapeutic potential." Thus, Nicoll itself appears to teach away from, not towards, a combination therapy of interferon-α with a nucleoside analog.

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LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

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The Examiner also stated that the present specification fails to enable the combination therapy of interferon-α and adefovir, because the working example in the specification discloses results for a patient receiving a combination therapy of interferon-α and lamivudine. The Examiner did not, however, reject any claims as non-enabled. The specification does enable the full scope of the claims. With regard to a possible combination therapy of interferon-α and adefovir specifically, the specification identifies adefovir as an example nucleoside analog, and states that it may be administered, for example, in a dose of between 5 and 30 mg per day. Specification at page 4, lines 34-35. The specification also states that interferon-α may be administered, for example, between 30 megaUnits and 15 megaUnits per week. Specification at page 5, lines 11-13. It would be a matter of routine for those skilled in the art to follow the guidance set forth in the specification to administer this combination therapy or any other specific type of therapy embraced by the claims.

LAW OFFICES
INNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

In light of the above, the pending claims should be in condition for allowance. Please grant any extensions of time required to enter this Response and charge any additional fees required to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON,
FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 21, 2001

By: _____
Steven J. Scott
Reg. No. 43,911

LAW OFFICES
NNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
ASHINGTON, DC 20005
202-408-4000

BCD | SJS

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: **Solco Walle SCHALM**

Application No.: 09/689,637 Group Art Unit: 1648

Filed: October 13, 2000 Examiner: L. Scheiner

For: COMBINED HEPATITIS B TREATMENT

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1. Status Inquiry

Dated August 12, 2003

Docket No.: 07873.0002

SJS/bag - please return to V. Simmons - Mail Drop **848**

8/13/03

PATENT
Customer Number 22,852
Attorney Docket No. 07873.0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Solco Walle SCHALM	)	Group Art Unit: 1648
	)	
Application No.: 09/689,637	)	Examiner: L. Scheiner
	)	
Filed: October 13, 2000	)	
	)	
For: COMBINED HEPATITIS B TREATMENT	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Status Inquiry

Applicants filed a response to an Office Action in this application on December 21, 2001. Applicants filed a copy of that Response again on May 15, 2003, at the suggestion of the Examiner. To date, applicants have not yet received any communication replying to the response filed on December 21, 2001.

In view of these circumstances, the undersigned attorney respectfully requests that the Office advise him of the status of this application as soon as possible in order to determine whether further action by the applicant is needed at this time.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 12, 2003

By: _____
Steven J. Scott
Reg. No. 43,911

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

Telephone
(202) 408-4000

Facsimile
(202) 408-4400

FACSIMILE TRANSMITTAL

Name: Examiner L. Scheiner	**Name:** Steven J. Scott
Firm: U.S. Patent and Trademark Office Group 1648	**Phone No.:** (202) 408-4231
	Fax # Verified by:
Fax No.: (703) 872 9306	**Date:** October 20, 2003
Phone No.:	**# Pages** (incl. this):
Subject: Application No. 09/689,637	**Confirmation - No**

Dear Ms. Scheiner:

A response was filed in this application on December 21, 2001. As you asked earlier this year, we re-submitted the response on May 15, 2003. Enclosed is a copy of the original response and re-submission of the response, together with copies of the PTO-stamped postcards. We look forward to receiving a reply from the U.S. Patent and Trademark Office.

Please contact me if you have any questions.

Certificate of Transmission:

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office on October 20, 2003.

Signature _____

Steven J. Scott
Reg. No. 43,911

If there is a problem with this transmission, notify fax room at (202) 408-4174 or the sender at the number above.